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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,142	11/24/2003	Dan T. Simionescu	CXU-379	4675
22827 7590 06/12/2008 DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER KHAN, AMINA S	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 06/12/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/722,142

Applicant(s)

SIMIONESCU ET AL.

Examiner

AMINA KHAN

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20, 21, 23, 24, 28-39 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) 30-39 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 23, 24, 28, 29 and 48-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. In view of the appeal brief filed on March 14, 2008, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

2. Claims 20,21,23,24,28-39 and 47-53 are pending. Claims 1-19, 22, 25-27 and 40-46 have been cancelled. Claims 30-39 and 47 have been withdrawn from consideration due to a non-elected invention.

3. The 35 U.S.C. 112 first paragraph rejection of claims 20,21 and 48 is maintained for the reasons set forth in the previous office action.

4. Applicant's arguments, see the appeal brief, filed March 14, 2008, with respect to the rejection(s) of 20-21, 23-24, 28-29, and 48-53 under 35 U.S.C. §103(a) as being unpatentable over Nimni et al. (US 4,378,224) in view of Nimni et al. (US 5,374,539) and claims 20-21,23-24, 28, and 48-52 under 35 U.S.C. §103(a) as obvious over Adkisson (US 6,645,764) in view of Asculai, et al. (US 6,444,222) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 20,21,23,24,28,29 and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tasiaux et al. (WO 01/21228) in view of Nguyen-Thien-Nhon (US 6,001,126).

Tasiaux et al. teach treating bovine pericardium with glutaraldehyde and gallotannic acid (page 35; lines 20-25 and page 36, lines 20-30). Tasiaux et al. further teach that these compounds provide the tissue with calcification resistance and stabilization (page 3 lines 1-5). Tasiaux et al. further teach the aldehyde crosslinks the

collagen of the tissue (page 14, line 40 to page 15, line 5). Tasiaux et al. further teach tannic acid may be used to treat the tissue (page 3, lines 15-20), that aortic valves or pericardium may be treated (page 2, lines 20-30) and that these treated tissues are suitable for implants (column 20, lines 39-41).

Tasiaux et al. do not teach cross-linked elastin or the concentration of the elastin.

Nguyen-Thien-Nhon teaches bioprosthetic implantable heart valves (column 2, lines 40-50) treated with a fixative or tanning agent such as glutaraldehyde for cross-linking the tissue (column 4, lines 60-67; column 5, lines 1-10) wherein the heart valves possess large amounts of collagen and elastin (column 1, lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the aortic valves taught by Tasiaux et al. would incorporate the elastin at the instantly claimed percentages because Nguyen-Thien-Nhon teach these valves possess large amounts of elastin and are conventionally fixed with chemical cross-linking agents such as glutaraldehyde. It would be expected that in the presence of elastin, a cross-linking agent such as tannic acid or glutaraldehyde would obviously provide a cross-linking of the elastin in the tissue. Furthermore, the disclosure of "large amounts of elastin" in the heart valves by Nguyen-Thien-Nhon would be expected to encompass the at least 10% instantly claimed. Additionally, one of ordinary skill in the art would be motivated to optimize the concentration of elastin to provide enhanced cross-linking of the tissue for enhanced stabilization and anti-calcification benefits of the implant.

Regarding the limitations "including a residue of the phenolic tannin cross-linking agent bound to and cross-linking the elastin of the fixed tissue" and ""including a residue of an aldehyde cross-linking agent bound to and cross-linking the cross-linked collagen of the fixed tissue" , it would be expected that treating similar tissues with similar compositions would be expected to provide similar crosslinking and binding results to the treated tissue.

### ***Response to Arguments***

7. Applicant's arguments filed regarding the 35 U.S.C. 112 first paragraph rejection of claims 20,21 and 48 have been fully considered but they are not persuasive. The applicant's arguments regarding the limitations of "including a residue of the phenolic tannin cross-linking agent bound to and cross-linking the elastin of the fixed tissue" and ""including a residue of an aldehyde cross-linking agent bound to and cross-linking the cross-linked collagen of the fixed tissue" are speculative. The examiner asserts that no evidence has been provided that a binding or crosslinking reaction between the residue of the phenolic-tannin agent and the elastin occur. Applicants' arguments are conclusory statements not supported by factual evidence, see *In re Lindner*, 457 F.2d 506, 173 USPQ 356 (CCPA 1972). Furthermore, the added limitation in the claim lacks literal basis in the specification as originally filed, see *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem.* 738 F.2d 453 (Fed. Cir. 1984).

### ***Conclusion***

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMINA KHAN whose telephone number is (571)272-5573. The examiner can normally be reached on Monday through Friday, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorna M Douyon/  
Primary Examiner, Art Unit 1796

/Amina Khan/  
Examiner, Art Unit 1796  
June 6, 2008

/VASUDEVAN S. JAGANNATHAN/  
Supervisory Patent Examiner, Art Unit 1796

